REMARKS

Pursuant to MPEP §713.04 Applicants' Attorney, Raymond E. Stauffer, hereby memorializes the substance of a telephonic interview had with the Examiner on April 10, 2003: Pursuant to pre-arranged appointment, Applicants' Attorneys, Elliot M. Olstein and Raymond E. Stauffer, called Examiner Gollamudi to discuss the Final Rejection of Claims 1-14, in light of the art of record. An agreement on patentable subject matter was not reached during this interview. But, it was agreed that an amendment presenting rewritten dependent claims in independent form, having dosage range elements distinguishing beyond the art of record, would be submitted and considered, in light of Applicants' willingness to cancel the then-pending independent claims, if such new claims were found allowable. It was further agreed that Applicants would reserve the right to re-present the cancelled claims in a continuation application.

Claims 1-14 have been rejected as being obvious under 35 U.S.C. §103 over U.S. Patent # 5,164,398 issued November 17, 1992 to Sims *et al.* (hereinafter "Sims"). Claims 7-14 are hereby cancelled and new claims 15-22 are substituted therefor, with new independent claims 15, 17, 19, & 21 having been rewritten as independent versions of cancelled dependent claims 7, 9, 11, & 13 respectively (new dependent claims 16, 18, 20, & 22 are virtually identical to cancelled dependent claims 8, 10, 12, & 14, but for their now being dependent upon new claims 15, 17, 19, & 21). As indicated in the interview, if new claims 15-22 are allowed, Applicants are willing to cancel claims 1-7. Accordingly, reconsideration of the application in light of the above amendment and the following remarks is requested.

Contrary to the Examiner's assertion, Sims does not fairly teach or suggest the specific combination of carbetapentane *tannate* and guaifenesin as the only active ingredients, as previously and instantly claimed. Much less does Sims suggest that combination in tablet or suspension form, in the *specific* ranges, or the *specific* amounts, as claimed in new claims 15-22 (Claims 15, 17, 19 & 21 are independent forms of dependent claims 7, 9, 11, & 13, respectively). Sims teaches a composition comprising *most essentially* the *S*-enantiomer of the analgesic / anti-inflammatory "ibuprofen," in combination with an antitussive, and, *optionally*, an expectorant. Significantly, Sims' unwavering focus is the treatment of ***pain*** and ***inflammation***:

> "This invention relates to pharmaceutical compositions for use in **the treatment of pain and inflammation** and the relief of cough cold symptoms..." (col. 1, lines 31-33, emphasis added).
>
> "This invention is also directed to a method of **treating pain and inflammation** and the relief of cough and cold symptoms..." (col. 1, lines 48-50, emphasis added).
>
> "This invention is also directed to a method of eliciting an onset hastened and enhanced response for **the treatment of pain and inflammation** and the relief of cough and cold symptoms..." (col 1, lines 65-68, emphasis added).
>
> "The composition and methods of the present invention may be used to **treat pain and inflammation, or pain alone or inflammation alone where only one is present**, along with the treatment of cough and cold symptoms." (column 2, lines 16-19, emphasis added).

When compared to Sims' mantra of treating "pain and inflammation" its concomitant mention of treating cough and cold symptoms would seem a less important afterthought to the artisan of ordinary skill. This primacy for treating pain and inflammation is all the more appreciated, in light of Sims' laudatory rhetoric regarding the *improved pain relief*

advantages that ibuprofen's *S*-enantiomer brings to antitussive combinations, over racemic ibuprofen formulations:

> "The utilization of (S)-ibuprofen in an analgesic/antitussive combination offers significant advantages over the combination of racemic ibuprofen with an antitussive. (S)-ibuprofen provides a **faster onset of pain relief and an enhanced degree of relief compared to racemic ibuprofen. These benefits are increased in an (S)-ibuprofen/antitussive combination as the antitussive may potentiate the action of the (S)-ibuprofen**. This has not heretofore been observed because the art has not proposed the combination of the (S)-ibuprofen enantiomer, absent (R)-ibuprofen, with an antitussive. **Furthermore the antitussive also may potentiate the duration of the analgesic and anti-inflammatory response.** The presence of the (R)-ibuprofen may blur the potentiated effect." (column 2, lines 46-59, emphasis added).

Clearly, the very *last* modification of Sims' teaching that Sims would commend to one of ordinary skill is the abandonment of Sims' ibuprofen component, and the Examiner can offer no Sims' citation to the contrary. In the alternative, reliance is placed upon MPEP §2144.04 for the proposition that the "omission of an element and its function is obvious if the function of the element is not desired." Beyond citing that platitude, the Examiner makes no attempt to analogize any of the three cases cited in that MPEP section with her pending rejection of the claims. Significantly, in each of Wu, Larson, and Kuhle, the Examiners had relied on secondary references, the teachings of which were essential in informing the obviousness determinations. Here, in contrast, the Examiner has offered no secondary references diverting from Sims very narrow teaching of treating pain and inflammation. Moreover, the Examiner wholly ignores her obligation to point out where Sims suggests the *desirability* of the modification that she proposes.

The mere fact that the prior art *can* be modified in the manner argued by the Examiner does not make the modification obvious "**unless the prior art suggested the *desirability* of the modification.**" In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984). The

Federal Circuit has consistently *reversed* obviousness determinations by the Board based upon Gordon's principle, while quoting the above cited Gordon language. In re Laskowski, 871 F.2d 115, at 117 (1989). In re Mills, 916 F.2d 680, at 682 (1990). In re Fritch, 972 F.2d 1260, at 1266 (1992). In re Debus, 1993 WL 513890, at **1 (1993). In re Brouwer, 77 F.3d 422, at 425 (1996). In re Butler, 1999 WL 164952, at **2 (1999). The Examiner's proposed modification is *not* obvious because the Examiner has failed to indicate where, within Sims' teaching, Sims suggests that it would be *desirable* to abandon its ibuprofen (analgesic / anti-inflammatory) component. This is because Sims offers no such suggestion. Indeed, the only component that Sims would suggest the abandonment of is the expectorant, which Sims refers to as being *optional*. And, that is because Sims, appropriately titled, is directed to *IBUPROFEN-ANTITUSSIVE COMBINATIONS,* and its above-quoted teachings would necessarily eschew *any* modification that included ibuprofen's abandonment.

The Examiner further asserts that insofar as the antitussive is selected from a Markush group of five, and the expectorant is selected from a Markush group of four, the "possible combinations" are "not unreasonable" and are "envisioned" by one of ordinary skill. While these buzz words are not the least bit related to the Graham v. Deere test for obviousness, Applicants would respond that Sims *also* teaches that the *salt* form of the antitussive (a claim element) may be one of eight, though not necessarily limited thereto (col., lines 37-39), and that the daily dosages of each component (also a claim element) run the gamut from 1mg to 50mg.—varying with the particular antitussive—and from 100mg. to 1000mg. without regard to the *optional* expectorant (col. 3, lines 31-38). These ranges are apparently not dependent upon which of the 11 different delivery forms

(further claim elements) that the artisan might select (col 3, lines 40-42).

The likelihood that the artisan would "envision" the exact combination of claim elements embodied in the newly-presented claims (15-22) is betrayed by the following observations. Five different antitussives, when multiplied by at least eight different salt forms, and further multiplied by four different expectorants, results in at least 160 different permutations of Sims' combined components! And that is only *after* the artisan has removed the ibuprofen. When that number is multiplied by 11 different delivery forms the permutations expand to 1760. When further multiplied by dosage ranges that could vary to potentially infinitesimal degrees the number becomes incalculable, thus transforming the artisan's search for a suggestion of the exact combination of elements of the newly-presented claims (15-22) from the proverbial search for the needle in a haystack into a search that would encompass an entire hayfield.

The newly presented tablet embodiment claims (15, 16, 19, & 20) are distinguished by carbetapentane tannate ranges (50mg.-75mg.), and amounts (60mg.) that are not disclosed for that *specific* antitussive in that *specific* salt form, by Sims' 1mg.-50mg. *general* antitusive range. The newly presented suspension embodiment claims (17, 18, 21, & 22) defining concentration of active ingredient by mg./5ml. of suspension, are also unsuggested by Sims, as Sims fails to indicate any active ingredient specificity with these, or any, concentration elements. Accordingly, Sims fails to teach or suggest the *specifically* claimed active ingredient combination, in the *specifically* claimed delivery forms, in either the *specifically* claimed dosage ranges or the *specifically* claimed dosage amounts, of new claims 15-22.

The Examiner posits that Sims "clearly *envisions* the use of both" carbetapentane

tannate and guaifenesin "as seen *throughout* the patent and *claim 5* in which guaifenesin is incorporated into the ibuprofen-antitussive composition." Upon closer inspection the Examiner will appreciate that the carbetapentane *tannate* salt is nowhere specifically mentioned in the Sims patent, and that the *carbetapentane* free base is referred to only in the Markush groups. Upon closer inspection of dependent claim 5, the Examiner will also appreciate that none of claims 1-4 provides antecedent basis for claim 5's "expectorant" element. Accordingly, the specifically claimed combination of carbetapentane *tannate* and guaifenesin, as the *only* active ingredients, is *not* clearly, or even remotely, *envisioned* by Sims. And the new claims (15-22) are at best attenuated derivations that might be possibly arrived at *if* the artisan were willing to ignore the *express* teaching of Sims, render Sims unfit for its intended purpose of treating pain and inflammation, and thereafter, arduously sift through a morass of formulations, infinite dosage ranges, and myriad delivery forms, all without guidance from the art.

Applicants' failure to offer "unexpected results" was mentioned both in the Office Action and during the teleconference, but the need for "an unexpected result becomes an issue only when the examiner has established a prima facie case of obviousness." Ex parte Duke, 1995 WL 1718860, *6 (Bd. Pat. App & Int.). Citing In re Piasecki, 745 F.2d 1468, 1472 (Fed Cir. 1984). In re Keller, 642 F.2d 413, 425 (CCPA 1981). Insofar as the Examiner has failed to show where Sims suggests her proposed modification, to arrive at the specific combination of actives, as the only actives, and the claimed amounts thereof, the Examiner has failed to establish that *prima facie* case of obviousness that would warrant Applicants' demonstration of unexpected results.

The specification's disclosure is rife with antecedent support for the newly-

presented claims. From its very beginning the specification conceives that the invention is the novel combination of only two active ingredients, *specifically* carbetapentane tannate and guaifenesin. See page 2, lines 1-2 under *Field of Invention* and page 3, lines 16-18 under *The Invention.* Additionally, the use of only carbetapentane tannate and guaifenesin, as active ingredients, is taught by the disclosed embodiments. See pages 4 and 5 and the first two ingredients listed under *Example 1* and *Example 2* respectively. The specific tablet and suspension ranges and amounts are also disclosed on pages 4 and 5. The element of pharmaceutically suitable carriers is also disclosed on pages 4 and 5.

In view of the foregoing, Applicants submit that the instant Amendment raises no new issues that would require further consideration or search, does not raise issues of new matter, and cancels as many claims as it presents. Moreover, by necessitating that the Board reconcile the Examiner's reliance on MPEP §2144.04 (not earlier argued) with Applicant's reliance upon Gordon and its progeny of Federal Circuit cases (earlier argued), the Amendment and Remarks place the application in better form by materially reducing and simplifying the *obviousness* issues for appeal. Accordingly, the Amendment should be entered in its entirety, or a Notice of Allowance should issue with regard to new claims 15-22, leaving Applicants to pursue the remaining claims in a continuation application.

The Office is hereby authorized to charge any fees due for independent claims in excess of three [37 C.F.R. 1.16(B)] to Deposit Account No.: 03-0678. It is believed that no further fee would otherwise be due. However, if any fee is due it should also be

charged to Deposit Account No.: 03-0678.

CERTIFICATE OF MAILING

Deposit Date: April 25, 2003

I hereby certify that this paper and the attachments hereto are being deposited today with the U.S. Postal Service with sufficient postage as First Class Mail to Addressee, under 37 CFR 1.8, on the date indicated above addressed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

4/25/03

Raymond E. Stauffer, Esq. **Date**

#177149 v1 - amendment after final rejection

Respectfully submitted,

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